Supplemental Table 1 – Baseline Demographics, Disease and Prior Treatment

appremental rable r Buseline r	l	apines,	Cohort				
	0	verall	i	iNKT iNKT/GM-CS			
	N	% %	N	%	N	%	
Sex	1 V	70	1 4	70	1 V	/0	
Male	7	77.8	2	66.7	5	83.3	
Female	2	22.2	1	33.3	1	16.7	
Race		22.2	1	33.3	1	10.7	
White	9	100.0	3	100.0	6	100.0	
Ethnicity	/	100.0		100.0	0	100.0	
Non-Hispanic	8	88.9	3	100.0	5	83.3	
Not known	1	11.1	3	100.0	1	16.7	
	1	11.1	_	-	1	10.7	
Initial stage IIB	1	111			1	16.7	
	1	11.1	1	33.3	1	10.7	
IIIA		11.1			- 1	167	
IIIC	2	22.2	1	33.3	1	16.7	
IV FGGG PG	5	55.6	1	33.3	4	66.7	
ECOG PS		00.0	2	100.0	۔	02.2	
0	8	88.9	3	100.0	5	83.3	
1	1	11.1	-	-	1	16.7	
Histology							
Superficial spreading melanoma	2	22.2	2	66.7	-		
Nodular melanoma	5	55.6	1	33.3	4	66.7	
Lentigo maligna melanoma	1	11.1	-	-	1	16.7	
Ocular melanoma	1	11.1	-	-	1	16.7	
Site of tumor							
Abdomen	1	11.1	1	33.3	-	-	
Back	1	11.1	-	-	1	16.7	
Eyes	1	11.1	-	-	1	16.7	
Lymph nodes axillary	1	11.1	-	-	1	16.7	
Right Arm	1	11.1	1	-	1	16.7	
Skin	3	33.3	1	33.3	2	33.3	
Skull/Face	1	11.1	1	33.3	-	_	
Had prior recurrence?							
Yes	9	100.0	3	100.0	6	100.0	
Lymph node dissection							
No	2	22.2	_	_	2	33.3	
Yes	7	77.8	3	100.0	4	66.7	
LN dissection positive?							
N/A or not done	2	22.2	_	_	2	33.3	
No	4	44.4	1	33.3	3	50.0	
Yes	3	33.3	2	66.7	1	16.7	

	N	Mean	S.D.	Min	Median	Max
Age (yrs)	9	61	11	49	54	76
Months since initial presentation	8	37	35	3	29	117
Number prior recurrences	9	1	0.4	1	1	2

Subject	<u>Pre-</u>	Post-	<u>%</u>	<u>Total</u>	<u>iNKT /</u>
	Expansion	Expansion	<u>CD4+</u>	<u>iNKT</u>	<u>Infusion</u>
	<u>% iNKT</u>	<u>% iNKT</u>	<u>iNKT</u>		
001	54	54	74	5.88E+8	1.35E+08
002	73	66	5	2.24E+8	7.19E+07
003	19	28	72	1.13E+07	3.60E+06
004	70	72	47	5.83E+07	2.49E+07
005	47	66	70	2.46E+8	1.53E+08
006	31	74	50	9.89E+8	1.85E+08
007	4	13	72	1.36E+8	2.73E+07
008	21	87	21	1.26E+9	2.17E+08
009	62	30	77	2.70E+8	7.28E+07

Supplemental Table 2. Summary of iNKT recovery & purity pre- & post-expansion The iNKT cell product was characterized as described in M&M.

Subject	%IFNy+	IFNy+	<u>%</u>	IFNγ+	<u>%IL-</u>	<u>%IL-</u>
	<u>CD4-</u>	<u>CD4-</u>	<u>IFNγ+</u>	<u>CD4+</u>	<u>4+</u>	<u>10+</u>
	<u>iNKT</u>	<u>iNKT</u>	<u>CD4+</u>	iNKT	<u>iNKT</u>	<u>iNKT</u>
		<u>MFI</u>	iNKT	MFI	<u>(MFI)</u>	<u>(MFI)</u>
001	52	10	43	6	NT	ND
002	52	10	NA	NA	ND	ND
003	60	3	70	10	15	NT
					(1.2)	
004	21	3.5	22	20	NT	ND
005	68	3.3	61	3.3	ND	ND
006	18	2.4	13	2.6	10	7
					(2.6)	(2.5)
007	11	2.0	24	0.7	17	ND
					(0.8)	
008	NT	NT	NT	NT	NT	NT
009	55	1.5	30	2.5	NT	NT

Supplemental Table 3. Functional activity of the iNKT product

Functional activity of the iNKT product was characterized as described in M&M. NA: not applicable (no significant CD4⁺ population); ND: not detectable; NT, not tested.

Toxicities – The worst grade of a reported toxicity is summarized for each patient. The following tables contain only those toxicities that were considered to be at least "possibly" related to therapy. All 9 patients reported toxicities that were related to treatment, all of grade 1 or 2. A complete listing of all toxicities, regardless of relatedness, is presented in the Appendix.

Supplemental Table 4a – Grade-2 Toxicities at Least Possibly Related to Treatment

CASE NUMBE				Toxicity Description		Attribution
R	Cohort	VISIT	Toxicity Category CTCAE v3.0	CTCAE v3.0	Attribution	$\sim Possible$
6	iNKT/GM-	Infusion 2	METABOLIC/LABORATORY	Hypophosphatemia	Possibly	Both
	CSF					
7	iNKT/GM-	Infusion 1	CONSTITUTIONAL	Fatigue	Possibly	Both
	CSF		SYMPTOMS			
8	iNKT/GM-	Infusion 2	CONSTITUTIONAL	Fatigue	Possibly	Both
	CSF		SYMPTOMS			
		Infusion 2	CONSTITUTIONAL	Constitutional- other	Possibly	Both
			SYMPTOMS			
		Infusion 2	DERMATOLOGY/SKIN	Injection site	Possibly	Both
				reaction		
9	iNKT/GM-	Infusion 2	DERMATOLOGY/SKIN	Pruritus/itching	Possibly	Both
	CSF					

Supplemental Table 4b – Grade-1 Toxicities at Least Possibly Related to Treatment

CASE			Toxicity Category CTCAE	Toxicity Description		Attribution ~
NUMBER	Cohort	VISIT	v3.0	CTCAE v3.0	Attribution	Possible
1	iNKT	Infusion 1	CONSTITUTIONAL	Constitutional- other Possi		iNKT Cells
			SYMPTOMS			
		Infusion 3	PAIN	Back- pain	Possibly	iNKT Cells
2	iNKT	Infusion 1	CONSTITUTIONAL	Odor (patient odor)	Definitely	
			SYMPTOMS			
		Infusion 1	CONSTITUTIONAL	Constitutional- other	Possibly	iNKT Cells
			SYMPTOMS			
		Infusion 1	DERMATOLOGY/SKIN	Pruritus/itching	Probably	
		Infusion 1	PAIN	Head/headache	Possibly	iNKT Cells
		Infusion 3	PAIN	Joint- pain	Possibly	iNKT Cells
		Infusion 3	PAIN	Muscle- pain	Possibly	iNKT Cells
		Infusion 3	PAIN	Throat/pharynx/larynx-	Possibly	iNKT Cells
				pain		
3	iNKT/GM-	Infusion 1	CARDIOVASUCLAR	Hypertension	Possibly	Both
	CSF		(GENERAL)			
		Infusion 1	DERMATOLOGY/SKIN	Pruritus/itching	Possibly	Both
		Infusion 2	BLOOD/BONE MARROW	Leukocytes	Probably	
		Infusion 2	DERMATOLOGY/SKIN	Injection site reaction	Definitely	
4	iNKT	Infusion 1	CARDIOVASUCLAR	Hypotension	Possibly	iNKT Cells
			(GENERAL)			
		Infusion 1	PAIN	Head/headache	Possibly	iNKT Cells

CASE IUMBER	Cohort	VISIT	Toxicity Category CTCAE v3.0	Toxicity Description CTCAE v3.0	Attribution	Attribution ~ Possible
		Infusion 2	CONSTITUTIONAL SYMPTOMS	Odor (patient odor)	Definitely	
		Infusion 2	ENDOCRINE	Hot flashes	Possibly	iNKT Cells
		Infusion 3	NEUROLOGY	Neurologic-other	Possibly	iNKT Cells
5 iNKT/GM- CSF		Infusion 2	CONSTITUTIONAL SYMPTOMS	Rigors/chills	Possibly	Both
		Infusion 2	DERMATOLOGY/SKIN	Pruritus/itching	Possibly	Both
		Infusion 2	DERMATOLOGY/SKIN	Rash/desquamation	Possibly	Both
		Infusion 2	PAIN	Joint- pain	Possibly	Both
		Infusion 2	PAIN	Muscle- pain	Possibly	Both
		Infusion 3	DERMATOLOGY/SKIN	Injection site reaction	Probably	
6	iNKT/GM-	Infusion 1	GASTROINTESTINAL	Constipation	Possibly	iNKT Cells
	CSF		CONSTITUTIONAL SYMPTOMS	Rigors/chills	Possibly	Both
		Infusion 2	GASTROINTESTINAL	Nausea	Possibly	Both
		Infusion 2	METABOLIC/LABORATO RY	Hyperglycemia	Possibly	Both
		Infusion 2	METABOLIC/LABORATO RY	Hypomagnesemia	Possibly	Both
		Infusion 2	PAIN	Muscle- pain	Possibly	Both
		Infusion 3	GASTROINTESTINAL	Anorexia	Possibly	Both
		Infusion 3	PAIN	Back- pain	Possibly	Both
		Infusion 3	PAIN	Joint- pain	Possibly	Both
		Infusion 3	PULMONARY/UPPER RESPIRATORY	Dyspnea	Possibly	Both
7	iNKT/GM- CSF		PULMONARY/UPPER RESPIRATORY	Cough	Possibly	Both
		Infusion 1	DERMATOLOGY/SKIN	Injection site reaction	Probably	
		Infusion 1	PAIN	Back- pain	Possibly	Both
		Infusion 1	PAIN	Muscle- pain	Possibly	GM-CSF
		Infusion 3	CONSTITUTIONAL SYMPTOMS	Fever w/o neutropenia	Possibly	Both
		Infusion 3	DERMATOLOGY/SKIN	Pruritus/itching	Probably	
		Infusion 3	PAIN	Throat/pharynx/larynx-pain	Possibly	Both
8	iNKT/GM- CSF	Infusion 2	CONSTITUTIONAL SYMPTOMS	Rigors/chills	Possibly	Both
		Infusion 2	GASTROINTESTINAL	Nausea	Possibly	Both
		Infusion 2	PAIN	Head/headache	Possibly	Both
		Infusion 3	DERMATOLOGY/SKIN	Pruritus/itching	Definitely	_
		Infusion 3	PAIN	Throat/pharynx/larynx- pain	Possibly	Both
		Infusion 3	PAIN	Pain-other	Definitely	
9	iNKT/GM-		BLOOD/BONE MARROW	Neutrophils		iNKT Cells
	CSF	Infusion 2	CONSTITUTIONAL SYMPTOMS	Fatigue	Possibly	Both

CASE			Toxicity Category CTCAE	Toxicity Description		Attribution ~
NUMBER	Cohort	VISIT	v3.0	CTCAE v3.0	Attribution	Possible
		Infusion 2	CONSTITUTIONAL	Odor (patient odor)	Definitely	
			SYMPTOMS			
		Infusion 2	DERMATOLOGY/SKIN	Injection site reaction	Definitely	
		Infusion 2	PAIN	Joint- pain	Possibly	Both
		Infusion 2	PAIN	Stomach- pain	Possibly	Both
		Infusion 3	PAIN	Muscle- pain	Possibly	GM-CSF
		Infusion 3	PULMONARY/UPPER	Nasal cavity/paranasal	Possibly	Both
			RESPIRATORY	sinus reaction		

Supplemental Table 5 – Number of Patients with Related Toxicities According to Category

Supplemental Table 5 – Number of Lac		Toxicity CTCAE	Grade
		1	2
Toxicity Category CTCAE v3.0	Toxicity Description CTCAE v3.0		
BLOOD/BONE MARROW	Leukocytes	1	-
	Neutrophils	1	-
CARDIOVASUCLAR (GENERAL)	Hypertension	1	-
	Hypotension	1	-
CONSTITUTIONAL SYMPTOMS	Constitutional- other	2	1
	Fatigue	1	2
	Fever w/o neutropenia	1	-
	Odor (patient odor)	3	-
	Rigors/chills	3	-
DERMATOLOGY/SKIN	Injection site reaction	4	1
	Pruritus/itching	5	1
	Rash/desquamation	1	-
ENDOCRINE	Hot flashes	1	-
GASTROINTESTINAL	Anorexia	1	-
	Constipation	1	-
	Nausea	2	-
METABOLIC/LABORATORY	Hyperglycemia	1	-
	Hypomagnesemia	1	-
	Hypophosphatemia	-	1
NEUROLOGY	Neurologic-other	1	-
PAIN	Back- pain	3	-
	Head/headache	3	-
	Joint- pain	4	-
	Muscle- pain	5	-
	Pain-other	1	
	Stomach- pain	1	
	Throat/pharynx/larynx- pain	3	
PULMONARY/UPPER RESPIRATORY	Cough	1	
	Dyspnea	1	_
	Nasal cavity/paranasal sinus		
	reaction	1	-

Supplemental Table 6 – DTH Skin Test

CASE NUMBER	Timepoint	Was DTH Given?	Location of Injection	Reaction at Injection Site?	Erythema?	Erythema area (cm**2)	Induration?	Induration area (cm**2)	Itching?
1	Baseline	Yes	Right arm	Yes	Yes	16.00	No		No
1	PI 3, Visit 2	Yes	Right arm	Yes	No		Yes	16.00	No
2	Baseline	Yes	Right arm	No	No		No		No
2	PI 3, Visit 2	Yes	Right arm	No	No		No		No
3	Baseline	Yes	Right arm	Yes	No	•	Yes	4.41	No
3	PI 3, Visit 2	Yes	Right arm	Yes	Yes	16.00	No		No
4	Baseline	Yes	Left arm	Yes	No	٠	Yes	1.44	No
4	PI 3, Visit 2	Yes	Left arm	Yes	No	•	Yes	2.25	No
5	Baseline	Yes	Left arm	Yes	Yes	8.40	Yes	8.40	No
5	PI 3, Visit 2	No		N/A	N/A		N/A		N/A
6	Baseline	Yes	Right arm	Yes	No		Yes†	N/A.	No
6	PI 3, Visit 2	Yes	Right arm	Yes	Yes	1.50	Yes	1.50	No
7	Baseline	Yes	Right arm	Yes	Yes	4.41	Yes	4.41	No
7	PI 3, Visit 2	Yes	Left arm	Yes	Yes	133.10	Yes	3.78	No
8	Baseline	Yes	Right arm	Yes	Yes	7.02	Yes	3.12	No
8	PI 3, Visit 2	Yes	Left arm	Yes	Yes	4.00	Yes	60.00	Yes
9	Baseline	Yes	Right arm	No	No	•	No		No
9	PI 3, Visit 2	Yes	Right arm	No			No		No

† Length = 1.5 cm, width missing.

Time on Study, Progression and Survival – Outcome data were updated on April 3, 2015. Median follow-up for this patient cohort is 63 months (95% CI 53 to 85 months). As of 4/3/15, three patients had died, and six had disease progression. All patients who died also had disease progression.

Supplemental Table 7 – Time on Treatment, Time on Study

Supplementar	Table 7 - Time	011	11000	1101109	1 1111	on Stu	u j
			Mea	S.D		Media	
		N	n		Min	n	Max
Weeks on Tx	Overall				13.		
		9	16.8	6.5	1	14.3	33.0
	Cohort				14.		
	iNKT	3	16.9	2.8	9	15.7	20.0
	iNKT/GM-				13.		
	CSF	6	16.7	8.0	1	13.4	33.0
Weeks on Study	Overall			32.	15.		127.
-		9	48.5	4	3	42.3	0
	Cohort			47.	44.		127.
	iNKT	3	72.4	3	7	45.6	0
	iNKT/GM-			16.	15.		
	CSF	6	36.5	3	3	40.6	59.9

Supplemental Table 8 – Response and Survival

				-	Cohort		
					iNKT/GM-		
	Ove	erall	iΝ	<i>VKT</i>	C_{k}^{c}	SF	
	N	%	N	%	N	%	
BOR		33.		66.			
PD	3	3	2	7	1	16.7	
SD		66.		33.			
	6	7	1	3	5	83.3	
Progression?		33.		33.			
No	3	3	1	3	2	33.3	
Yes		66.		66.			
	6	7	2	7	4	66.7	
Vital Status		66.		66.			
Alive	6	7	2	7	4	66.7	
Died		33.		33.	·	_	
	3	3	1	3	2	33.3	

Supplemental Appendix

Table SA1 – Grade-5 Toxicities (all relatedness)

			Toxicity								
			Category								
CASE			CTCAE								
NUMBER	Cohort	VISIT	v3.0	Toxicity Description CTCAE v3.0	Attribution	Attribution ~ Possible					
5	iNKT/GM-	Infusion 3	DEATH	Death - disease progression NOS	Not related						
	CSF										

Table SA2 – Grade- 4 Toxicities (all relatedness)

CASE				Toxicity Description		
NUMBER	Cohort	VISIT	Toxicity Category CTCAE v3.0	CTCAE v3.0	Attribution	Attribution ~ Possible
5	iNKT/GM-	Infusion 3	HEPATOBILIARY/PANCREA	Liver dysfunction/failure	Not related	
	CSF		S	J		
		Infusion 3	RENAL/GENITOURINARY	Renal failure	Not related	

Table SA3 – Grade-3 Toxicities (all relatedness)

CASE NUMBER				Toxicity Description CTCAE v3.0 Back- pain	Attribution Unlikely	Attribution ~ Possible
3		Infusion 3	PAIN	Bone- pain	Unlikely	
8	iNKT/GM- CSF	Follow-Up 1	METABOLIC/LABORATORY	Hyponatremia	Unlikely	

Table SA4 – Grade-2 Toxicities (all relatedness)

	1 abic 51	17 Grade 2	a Toxicities (all Telateuness)			
CASE NUMBE						Attribution ~
R	Cohort	VISIT	Toxicity Category CTCAE v3.0	Toxicity Description CTCAE v3.0	Attribution	Possible
2	iNKT	Follow-Up 1	INFECTION	Infection w/ unk ANC skin (cellulitis)	Unlikely	
5	iNKT/GM- CSF		GASTROINTESTINAL	Distention/bloating- abdominal	Unlikely	
5	iNKT/GM- CSF	Infusion 3	METABOLIC/LABORATORY	Alkaline phosphatase	Not related	
5	iNKT/GM- CSF	Infusion 3	METABOLIC/LABORATORY	ALT- SGPT	Not related	
5	iNKT/GM- CSF	Infusion 3	METABOLIC/LABORATORY	AST- SGOT	Not related	
5	iNKT/GM- CSF	Infusion 3	METABOLIC/LABORATORY	Hyperkalemia	Not related	
5	iNKT/GM- CSF	Infusion 3	PULMONARY/UPPER RESPIRATORY	Atelectasis	Not related	
6	iNKT/GM- CSF	Infusion 2	METABOLIC/LABORATORY	Hypophosphatemia	Possibly	Both
7	iNKT/GM- CSF	Infusion 1	CONSTITUTIONAL SYMPTOMS	Fatigue	Possibly	Both
8	iNKT/GM- CSF	Infusion 2	CONSTITUTIONAL SYMPTOMS	Fatigue	Possibly	Both

CASE NUMBE R	Cohort	VISIT	Toxicity Category CTCAE v3.0	Toxicity Description CTCAE v3.0	Attribution	Attribution ~ Possible
8	iNKT/GM-	Infusion 2	CONSTITUTIONAL	Constitutional- other	Possibly	Both
8	CSF	illusion 2	SYMPTOMS	Constitutional- other	1 0551019	Dom
8	iNKT/GM- CSF	Infusion 2	DERMATOLOGY/SKIN	Injection site reaction	Possibly	Both
9	iNKT/GM- CSF	Infusion 2	DERMATOLOGY/SKIN	Pruritus/itching	Possibly	Both
9	iNKT/GM- CSF	Infusion 2	METABOLIC/LABORATORY	Hyperglycemia	Not related	
	Table SA	\5 – Grade-1	Toxicities (all relatedness)			
CASE		VISIT				Attribution ~
VUMBER	Cohort	REFNAME	Toxicity Category CTCAE v3.0	Toxicity Description CTCAE v3.0	Attribution	Possible
1	iNKT	Follow-Up 1	DERMATOLOGY/SKIN	Rash/desquamation	Unlikely	
1	iNKT	Follow-Up 1	LYMPHATICS	Edema limb	Not related	
1	iNKT	Follow-Up 1	PAIN	Dental/teeth/peridontal- pain	Not related	
1	iNKT	Follow-Up 2	PAIN	Muscle- pain	Not related	
1	iNKT	Infusion 1	CONSTITUTIONAL SYMPTOMS	Constitutional- other	Possibly	iNKT Cells
1	iNKT	Infusion 3	PAIN	Back- pain	Possibly	iNKT Cells
2	iNKT	Follow-Up 1	CONSTITUTIONAL SYMPTOMS	Fatigue	Unlikely	
2	iNKT	Follow-Up 1	GASTROINTESTINAL	Diarrhea w/o prior colostomy	Unlikely	
2		Follow-Up 1	GASTROINTESTINAL	Nausea	Unlikely	
2		Follow-Up 1	MUSCULOSKELETAL/SOFT TISSUE	Musculoskeletal/soft tissue-other	Unlikely	
2	iNKT	Follow-Up 1	SYNDROMES	Syndromes-other	Unlikely	
2	iNKT	Infusion 1	CONSTITUTIONAL SYMPTOMS	Odor (patient odor)	Definitely	
2	iNKT	Infusion 1	CONSTITUTIONAL SYMPTOMS	Constitutional- other	Possibly	IiNKT Cells
2	iNKT	Infusion 1	DERMATOLOGY/SKIN	Pruritus/itching	Probably	
2	iNKT	Infusion 1	PAIN	Head/headache	Possibly	iNKT Cells
2	iNKT	Infusion 3	PAIN	Joint- pain	Possibly	iNKT Cells
2	iNKT	Infusion 3	PAIN	Muscle- pain	Possibly	iNKT Cells
2		Infusion 3	PAIN	Throat/pharynx/larynx- pain	Possibly	iNKT Cells
3	iNKT/GM- CSF	Infusion 1	CARDIOVASUCLAR (GENERAL)	Hypertension	Possibly	Both
3	iNKT/GM- CSF	Infusion 1	DERMATOLOGY/SKIN	Pruritus/itching	Possibly	Both
3	iNKT/GM- CSF	Infusion 2	BLOOD/BONE MARROW	Leukocytes	Probably	
3	iNKT/GM- CSF	Infusion 2	DERMATOLOGY/SKIN	Injection site reaction	Definitely	
4	iNKT	Follow-Up 1	NEUROLOGY	Neuropathy-sensory	Unlikely	
4	iNKT	Infusion 1	CARDIOVASUCLAR (GENERAL)	Hypotension	Possibly	iNKT Cells
4	iNKT	Infusion 1	PAIN	Head/headache	Possibly	iNKT Cells
4	iNKT	Infusion 2	CONSTITUTIONAL SYMPTOMS	Odor (patient odor)	Definitely	
4	iNKT	Infusion 2	ENDOCRINE	Hot flashes	Possibly	iNKT Cells

CASE VUMBER	Cohort	VISIT REFNAME	Toxicity Category CTCAE v3.0	Toxicity Description CTCAE v3.0	Attribution	Attribution - Possible
4		Infusion 3	NEUROLOGY	Neurologic-other	Possibly	iNKT Cells
5		Infusion 2	CONSTITUTIONAL SYMPTOMS	Rigors/chills	Possibly	
5	iNKT/GM- CSF	Infusion 2	DERMATOLOGY/SKIN	Pruritus/itching	Possibly	Both
5	iNKT/GM- CSF	Infusion 2	DERMATOLOGY/SKIN	Rash/desquamation	Possibly	Both
5	iNKT/GM- CSF	Infusion 2	GASTROINTESTINAL	Flatulence	Unlikely	
5	iNKT/GM- CSF	Infusion 2	PAIN	Joint- pain	Possibly	Both
5	iNKT/GM- CSF	Infusion 2	PAIN	Muscle- pain	Possibly	Both
5	iNKT/GM- CSF	Infusion 3	BLOOD/BONE MARROW	Hemoglobin	Unlikely	
5	iNKT/GM- CSF	Infusion 3	CARDIOVASCULAR (ARRHYTHMIA)	Arrhythmia-other	Not related	
5	iNKT/GM- CSF	Infusion 3	COAGULATION	INR	Not related	
5	iNKT/GM- CSF	Infusion 3	COAGULATION	PTT	Not related	
5	iNKT/GM- CSF	Infusion 3	DERMATOLOGY/SKIN	Injection site reaction	Probably	
5	iNKT/GM- CSF	Infusion 3	METABOLIC/LABORATORY	Bilirubin	Not related	
5	iNKT/GM- CSF	Infusion 3	METABOLIC/LABORATORY	Hypocalcemia	Unlikely	
5	iNKT/GM- CSF	Infusion 3	METABOLIC/LABORATORY	Proteinuria	Unlikely	
5	iNKT/GM- CSF	Infusion 3	METABOLIC/LABORATORY	Hyponatremia	Unlikely	
5	iNKT/GM- CSF	Infusion 3	PULMONARY/UPPER RESPIRATORY	Cough	Unlikely	
6	CSF	Follow-Up 1	SYMPTOMS	Fatigue	Unlikely	
6	CSF		DERMATOLOGY/SKIN	Induration/fibrosis	Unlikely	
6	iNKT/GM- CSF	Infusion 1	GASTROINTESTINAL	Constipation	Ž	iNKT Cells
6	iNKT/GM- CSF	Infusion 2	CONSTITUTIONAL SYMPTOMS	Rigors/chills	Possibly	
6	iNKT/GM- CSF	Infusion 2	GASTROINTESTINAL	Nausea	Possibly	Both
6	iNKT/GM- CSF	Infusion 2	METABOLIC/LABORATORY	Hyperglycemia	Possibly	
6	iNKT/GM- CSF		METABOLIC/LABORATORY	Hypomagnesemia	Possibly	Both
6	iNKT/GM- CSF	Infusion 2	PAIN	Muscle- pain	Possibly	Both
6	iNKT/GM- CSF	Infusion 3	GASTROINTESTINAL	Anorexia	Possibly	Both

CASE NUMBER	Cohort	VISIT REFNAME	Toxicity Category CTCAE v3.0	Toxicity Description CTCAE v3.0	Attribution	Attribution Possible
6	iNKT/GM- CSF		PAIN	Back- pain	Possibly	Both
6	iNKT/GM- CSF	Infusion 3	PAIN	Joint- pain	Possibly	Both
6	iNKT/GM- CSF	Infusion 3	PULMONARY/UPPER RESPIRATORY	Dyspnea	Possibly	Both
7	iNKT/GM- CSF	Follow-Up 1	PULMONARY/UPPER RESPIRATORY	Cough	Possibly	Both
7	iNKT/GM- CSF	Infusion 1	ALLERGY/IMMUNOLOGY	Allergy-other	Unlikely	
7	iNKT/GM- CSF	Infusion 1	DERMATOLOGY/SKIN	Injection site reaction	Probably	
7	iNKT/GM- CSF	Infusion 1	PAIN	Back- pain	Possibly	Both
7	iNKT/GM- CSF	Infusion 1	PAIN	Muscle- pain	Possibly	GM-CSF
7	iNKT/GM- CSF	Infusion 3	CONSTITUTIONAL SYMPTOMS	Fever w/o neutropenia	Possibly	Both
7	iNKT/GM- CSF	Infusion 3	DERMATOLOGY/SKIN	Pruritus/itching	Probably	
7	iNKT/GM- CSF	Infusion 3	GASTROINTESTINAL	Anorexia	Unlikely	
7	iNKT/GM- CSF	Infusion 3	PAIN	Throat/pharynx/larynx- pain	Possibly	Both
8	iNKT/GM- CSF	Infusion 2	CONSTITUTIONAL SYMPTOMS	Rigors/chills	Possibly	Both
8	iNKT/GM- CSF	Infusion 2	GASTROINTESTINAL	Nausea	Possibly	Both
8	iNKT/GM- CSF	Infusion 2	PAIN	Head/headache	Possibly	Both
8	iNKT/GM- CSF	Infusion 3	DERMATOLOGY/SKIN	Pruritus/itching	Definitely	
8	iNKT/GM- CSF	Infusion 3	PAIN	Throat/pharynx/larynx- pain	Possibly	Both
8	iNKT/GM-	Infusion 3	PAIN	Pain-other	Definitely	
9	iNKT/GM- CSF	Follow-Up 2	NEUROLOGY	Dizziness	Unlikely	
9	iNKT/GM- CSF	Infusion 1	BLOOD/BONE MARROW	Leukocytes	Not related	
9	iNKT/GM- CSF	Infusion 2	BLOOD/BONE MARROW	Neutrophils	Possibly	iNKT Cells
9	iNKT/GM- CSF	Infusion 2	CONSTITUTIONAL SYMPTOMS	Fatigue	Possibly	Both
9	iNKT/GM- CSF	Infusion 2	CONSTITUTIONAL SYMPTOMS	Odor (patient odor)	Definitely	
9	iNKT/GM- CSF	Infusion 2	DERMATOLOGY/SKIN	Injection site reaction	Definitely	
9	iNKT/GM- CSF	Infusion 2	PAIN	Joint- pain	Possibly	Both
9	iNKT/GM- CSF	Infusion 2	PAIN	Stomach- pain	Possibly	Both

CASE		VISIT				Attribution ~
<i>VUMBER</i>	Cohort	REFNAME	Toxicity Category CTCAE v3.0	Toxicity Description CTCAE v3.0	Attribution	Possible
9	iNKT/GM-	Infusion 3	PAIN	Muscle- pain	Possibly	GM-CSF
	CSF					
9	iNKT/GM-	Infusion 3	PULMONARY/UPPER	Nasal cavity/paranasal sinus	Possibly	Both
	CSF		RESPIRATORY	reaction	-	